ingredients, identified in § 331.11(c), must continue to bear both warnings required by § 330.1(g).

Because this final rule relates only to warnings for OTC antacid and antiflatulent drug products, the changes in the "exclusivity" policy that were recently published in the **Federal Register** of May 1, 1986 (51 FR 16258) do not apply to this document.

One comment was submitted in response to the agency's request for specific comment on the economic impact of this rulemaking (49 FR 14909). The comment argued that marketers of sodium bicarbonate products would suffer unjustifiable, irreparable economic harm if sodium bicarbonate products were required to bear the "keep out of reach of children" statement because the statement would deter consumers from purchasing the product for use as a refrigerator deodorant, baking ingredient, etc. Because this final rule exempts powder forms of sodium bicarbonate intended primarily for other than drug uses from the "keep out of reach of children" statement, the comment's concern is moot. The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC antacid and antiflatulent drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act, Public Law 96–354. That assessment included a discretionary Regulatory Flexibility Analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antacid and antiflatulent drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 331

Labeling, OTC drugs, Antacid drug products.

21 CFR Part 332

Labeling, OTC drugs, Antiflatulent drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 331 and 332 as follows:

PART 331—ANTACID PRODUCTS FOR OVER-THE-COUNTER (OTC) HUMAN USE

1. The authority citation for 21 CFR Part 331 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

§ 331.11 [Amended]

2. In Part 331, § 331.11 *Listing of specific active ingredients* is amended in paragraph (k)(1) by revising the last sentence to read:

* * * * *

(k) * * *

(1) * * * That part of the warning required by § 330.1(g), which states, "Keep this and all drugs out of the reach of children" is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.

3. In Part 331, § 331.30 is amended by adding new paragraph (g) to read as follows:

§ 331.30 Labeling of antacid products.

* * * * *

(g) *Exemption from the general accidental overdose warning.* The labeling for antacid drug products containing the active ingredients identified in § 331.11(a), (b), and (d) through (m); permitted combinations of these ingredients provided for in § 331.10; and any of these ingredients or combinations of these ingredients in combination with simethicone (identified in § 332.10 of this chapter and provided for in § 331.15(c)), are exempt from the requirement in § 300.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." With the exception of sodium bicarbonate powder products identified in § 331.11(k)(1), the labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

PART 332—ANTIFLATULENT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

4. The authority citation for 21 CFR Part 332 continues to read as follows:

Authority: Secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371); 5 U.S.C. 553; 21 CFR 5.11.

5. In Part 332, § 332.30 is amended by adding new paragraph (c) to read as follows:

§ 332.30 Labeling of antiflatulent products.

* * * * *

(c) *Exemption from the general accidental overdose warning.* The labeling for antiflatulent drug products containing simethicone identified in § 332.10 and antacid/antiflatulent combination drug products provided for in § 332.15, containing the active ingredients identified in § 331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in § 330.1(g) of this chapter that the labeling bear the general warning statement "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling must continue to bear the first part of the general warning in § 330.1(g) of this chapter, which states, "Keep this and all drugs out of the reach of children."

Dated: May 3, 1986.

Frank E. Young,

Commissioner of Food and Drugs.

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